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International Journal of Surgery Open 24 (2020) 57–63

Contents lists available at ScienceDirect

International Journal of Surgery Open

journal homepage: www.elsevier.com/locate/ijso

Research Paper

Hemostatic efficacy of an advanced bipolar sealer in open gynecologic, thoracic, and colectomy procedures: A prospective cohort study

Jeanne Schilder [a], David Anderson [b], Fatima Shah [c], Bryan Holcomb [a], Ahmar Shah [c], Grant Fullarton [d], Shazad Ashraf [e], Scott Fegan [f], Hugh Paterson [b], Michael L. Schwiers [g], David W. Singleton [g, *], Jason R. Waggoner [g], Raymond Fryrear II [g], Bruce W. Robb [a]

[a] Indiana University Health, 550 N University Blvd, Indianapolis, IN 46202, USA
[b] Western General Hospital, Crewe Rd S, Edinburgh, EH4 2XU, United Kingdom
[c] Yeovil District Hospital, Higher Kingston, Yeovil, BA21 4AT, United Kingdom
[d] Glasgow Royal Infirmary, 84 Castle St, Glasgow, G4 0SF, United Kingdom
[e] University Hospitals Birmingham, Queen Elizabeth Hospital, Mindelsohn Way, Birmingham, B15 2TH, United Kingdom
[f] Royal Infirmary of Edinburgh, 51 Little France Cres, Edinburgh EH16 4SA, United Kingdom
[g] Ethicon Endo-Surgery, Inc., 4545 Creek Rd, Blue Ash, OH 45242, USA

ARTICLE INFO

Article history:
Received 25 March 2020
Accepted 27 March 2020
Available online 5 April 2020

Keywords:
Advanced bipolar
ENSEAL
Hemostasis
Vessel transection
Open surgery

ABSTRACT

Background: An advanced bipolar (ABP) tissue sealer designed for division of major vessels in open procedures was evaluated in a prospective post-market study. The objective was to provide clinical data for assessment of vessel transection, hemostatic performance and ease of use of the ABP device during open colectomy, gynecologic, and thoracic operations.

Materials and methods: The ABP test device was used in colectomy (n = 36), gynecologic (n = 44), and thoracic (n = 21) procedure groups. Vessels transected with the ABP device were graded intraoperatively on a hemostasis scale of 1–4, defined as follows: Grade1, no bleeding; Grade 2, minor bleeding with no intervention; Grade 3, minor bleeding requiring touchup with the test device or monopolar cautery; and Grade 4, significant bleeding requiring intervention with any additional hemostatic product. The primary performance measure was the percentage of vessels that achieved hemostasis grades ≤3. The primary safety endpoint was the summarization of all ABP device-related adverse events (AEs).

Results: For all three procedure groups together, 302 (96.2%) of 314 total vessel transections were scored as hemostasis grades ≤ 3, including 270 (86.0%) that were rated Grade 1. Twelve transections (3.8%) were Grade 4, which included 9 vessels transected in the gynecologic group and 3 in the thoracic group. Three subjects experienced a total of 4 device-related AEs, consisting of hematoma, hypotension, procedural pain, and superficial thermal burn. All 4 device-related AEs were mild in severity.

Conclusion: The advanced bipolar device exhibited effective hemostasis, an acceptable safety profile, and ease of use during colectomy, thoracic, and gynecologic procedures.

Trial registry number: ClinicalTrials.gov, NCT034411.

1. Introduction

Bipolar electrosurgical devices are widely used in a variety of surgical specialties for sealing and transection of blood vessels as well as dissection of tissues. In clinical use, advanced bipolar technology may have advantages relative to other surgical approaches. For example, current flow is largely confined to tissue held between the instrument's jaws, which promotes effective vessel sealing and reduced risk of thermal injury. Investigators have found that in abdominal or laparoscopic hysterectomy procedures, bipolar sealers were associated with reduced operative time, lower blood loss, less postoperative pain, and similar or better clinical outcomes versus conventional suture ligation of blood vessels [1–7]. A comparative study of laparoscopic colorectal resections using bipolar sealing versus clips and staplers found the mean time needed for vascular pedicle control was significantly reduced with the bipolar device [8]. In another study of colorectal surgery, intraoperative bleeding from the inferior mesenteric artery (IMA) was observed in 6 of 400 (1.5%)

* Corresponding author.
E-mail address: dsingl12@its.jnj.com (D.W. Singleton).

https://doi.org/10.1016/j.ijso.2020.03.007

subjects following ligation of this vessel with an advanced bipolar device [9]. The authors concluded that the bipolar device could be safely employed for vascular control of the IMA. For patients undergoing Ivor-Lewis esophagectomy, advanced bipolar sealers were associated with lower intraoperative bleeding and faster operative times compared to conventional hemostatic clamp and tie methods [10,11]. Taken together, these studies suggest effective use of bipolar technology with regard to hemostatic control.

The advanced bipolar (ABP) device evaluated in this study was specifically designed for open procedures involving division of major vessels. The device is used for tissue dissection, grasping, and transection of vasculature in general, gynecologic, thoracic and vascular surgeries and may be used to seal and transect vessels (arteries, veins, pulmonary vasculature, lymphatics) up to and including 7 mm in diameter. Features include 360° shaft rotation for easier access to targeted tissue, enhanced ergonomics, and independent sealing and cutting functions. In initial bench-top and preclinical studies, the ABP device exhibited similar sealing strength of porcine vessels compared to another advanced bipolar instrument [12]. Hemostasis at the distal tip was significantly better for the ABP versus the comparator device, when each was applied to thick mesentery tissue. The purpose of the current study was to evaluate vessel transection, hemostatic performance and ease of use of the ABP device in a post-market clinical setting, in three open procedure groups: colectomy, gynecologic, and thoracic.

2. Methods

2.1. Study design

This study was a prospective, multicenter, single-arm, cohort analysis of procedures performed with an ABP device (ENSEAL® X1 Large Jaw Tissue Sealer, Ethicon Endo-Surgery, Inc., Cincinnati OH, USA), at 6 total institutions in the United Kingdom and USA. The study was carried out to provide post market clinical follow-up data on performance and safety of the device. The protocol and consent form were approved by each investigator's Institutional Review Board or Independent Ethics Committee. The study was registered with ClinicalTrials.gov (registry number NCT03441178) and conducted in accordance with Good Clinical Practice and the Declaration of Helsinki, as well as any other applicable local, state and federal requirements. Participating surgeons carried out the operations in accordance with their own standard surgical approach, using the ABP per its instructions for use. Each surgeon/investigator underwent training with the ABP test device prior to the study. During the study, more than one surgeon may have participated per case, but only one investigator utilized the test device in any given surgery. The protocol included a minimum of 3 visits: screening within 8 weeks prior to surgery, performance of the procedure through discharge, and a postoperative visit or phone call approximately 4 weeks after the procedure.

2.2. Subject Selection and procedure groups

In order to generate a representative patient sample, consecutive subjects scheduled to undergo an elective surgery from the proposed procedure groups were considered for participation in the study. Informed written consent was obtained for all subjects. A total of 100 subjects were planned to be enrolled, including a minimum of 30 colectomy procedures, 30 gynecologic procedures, and 20 thoracic procedures. The remaining 20 subjects were enrolled into any of the three procedural groups. Subjects were consented and screened anytime between scheduling of the operation and hospital admission. They were considered enrolled at the time of the first attempted vessel transection with the ABP device. Inclusion criteria were: at least one planned vessel to be transected with the ABP; willingness to consent and comply with study-related evaluations and treatment schedule; minimum age of 18 years. Criteria for exclusion were concurrent enrollment in a different clinical study, or any condition (physical or psychological) that would impair study participation. Elective open colectomy, gynecologic, or thoracic procedures were performed per each institution's standard of care approach, where the ABP device was utilized for vessel sealing and transection.

2.3. Performance and safety endpoints

The primary performance endpoint was the percentage of blood vessels transected using the ABP device in which hemostasis was achieved without the need for additional hemostatic products (e.g. hemoclips, staples, sutures, fibrin sealants, other advanced energy). Either no bleeding at the transection site, or minor bleeding that may require touch-up with the ABP device or a monopolar device were considered successful hemostasis and counted in this percentage. The primary endpoint was determined separately for each procedure group and for the entire subject set and was based on an assessment of hemostasis for all vessels transected with the test device. Each vessel transection was counted and graded for hemostasis intraoperatively. The hemostasis scale was defined as: Grade 1, no bleeding at the transection site; Grade 2, minor bleeding at the transection site that does not require intervention; Grade 3, minor bleeding at the transection site requiring touch-up with the ABP test device or monopolar cautery; Grade 4, significant bleeding (e.g., pulsatile blood flow, venous pooling) requiring intervention such as extensive coagulation or ligation with additional hemostatic products including hemoclips, staples, sutures, fibrin sealants, or another advanced energy device. Secondary endpoint measures were the distribution of vessel hemostasis grades in each procedure group, the incidence of ABP touch-ups for Grade 3, and incidence of specific types of Grade 4 interventions required to obtain hemostasis. The primary safety endpoint was the summarization of all test device-related adverse events (AEs), which were assessed for seriousness, severity, action taken, and outcome. In addition, investigators were asked to complete questionnaires to assess their experience with the study device. These included a short device questionnaire after each surgery, and a longer questionnaire following each investigator's second procedure in the study.

2.4. Statistical methods

The study planned to enroll a sample size of at least 100 patients, which was considered sufficient for a descriptive summary of performance endpoints within each procedural group. This was a single-arm study (no comparator device), and thus the sample size was not statistically sized. Estimation of endpoints was performed using 95% confidence intervals. At least 2 vessels were expected to be transected with the ABP test device per procedure, providing a minimum of 60 transections in each of the colorectal and gynecologic groups, and 40 within the thoracic procedures. The analysis sets used for summarization of performance and safety endpoints included all patients in whom the test device was utilized during the procedure. Performance and safety endpoints were summarized separately for each procedure group, as well as for the entire pooled subject set.

3. Results

3.1. Subject selection and demographic data

A total of 108 subjects were screened for enrollment, and 101 underwent surgery in one of the three procedure groups including

36 colectomy, 44 gynecologic, and 21 thoracic procedures. (Fig. 1). The study covered the period from March 13, 2018 (date of first enrollment) through August 30, 2019 (last postoperative visit). All subjects in whom the ABP device was used for transection of at least one blood vessel were included for analysis. Ninety-nine (98.0%) subjects completed the study through the final post-operative visit. One from the gynecologic group died during the study due to an acute ischemic bowel event that was considered unrelated to the test device. One thoracic subject underwent a gastric procedure that was not defined in the protocol. Table 1 lists demographic data for the subject population. Mean age was 61.8 years (range 28.0–89.0), with thoracic subjects' average age being older than the other two groups. A majority in each procedure group (95.0% overall) were White and 57.5% of overall subjects were current or former smokers. Body mass index was similar between groups.

3.2. Specific procedures and indications

Table 2 summarizes the types of operations performed within each group. The open colectomy group included multiple left-sided procedures (e.g. low anterior resection, sigmoid colectomy, and Hartmann's operation) which accounted for 47.2% of the surgeries. Right-sided colectomies were performed in 9 (25.0%) cases. In the gynecologic subjects, total abdominal hysterectomy was performed in 25 (56.8%) surgeries in combination with salpingo-oophorectomy or salpingectomy. The thoracic procedures consisted predominantly of transthoracic esophagectomies in 15 (71.4%), which included Ivor-Lewis (n = 14) and three-field (n = 1) techniques. The most common disease indication in the colectomy group was colorectal cancer, which was present in 22 of 36 cases (61.6%), followed by inflammatory bowel disease (Crohn's or Ulcerative colitis) in 6 (16.7%), and colon polyps or other conditions in 8 (22.2%) subjects. Among the gynecologic group, indications included ovarian cancer in 18 of 44 (40.9%) procedures, ovarian cyst in 6 (13.6%), prolapse in 6 (13.6%), uterine cancer in 4 (9.1%), and abnormal bleeding, fibroids, or other conditions in 10 (22.7%) procedures. In the thoracic group, esophageal cancer was the primary indication in 15 of 21 (71.4%) subjects, followed by benign esophageal disease or other conditions in 6 (28.6%) cases.

3.3. Hemostasis grading and operative data

The total number of arteries and veins transected and hemostasis grading for each procedure group are summarized in Table 3. Of 314 total vessels transected, 302 (96.2%) achieved Grade 3 or lower (better) hemostasis scores, with 11 (3.5%) vessels requiring at least one hemostatic touchup (Grade 3 hemostasis). Compression was used three times, while monopolar energy or the ABP device were used in six and eight instances, respectively for touchups. Analyses of each procedure group showed that Grade 3 or lower hemostasis scores were achieved for 94.2%, 96.7%, and 100.0% of transections in gynecologic, thoracic, and colectomy procedures, respectively. Across all procedures, 86.0% of transections were rated as Grade 1 (i.e. no bleeding at the transection site). The mean (median) intraoperative blood loss for each procedure group was ≤437 (300) ml. Table 4 summarizes the Grade 4 transections reported for the entire subject set. Across all procedures there were 12 (3.8%) Grade 4 hemostasis ratings. No Grade 4 ratings were observed in the colectomy group. In gynecologic procedures there were 9 (5.8%) Grade 4 vessel transections, including eight occurrences in uterine arteries. For all uterine artery transections (left + right), Grade 4 hemostasis was observed in 8 of 68 (11.8%) vessels. Other Grade 4 hemostasis events occurred in 1 of 66 (1.5%) ovarian arteries, and 3 vessels in thoracic procedures: 2 of 70 (2.9%) short gastric and 1 of 15 (6.7%) gastroepiploic. Sutures were used

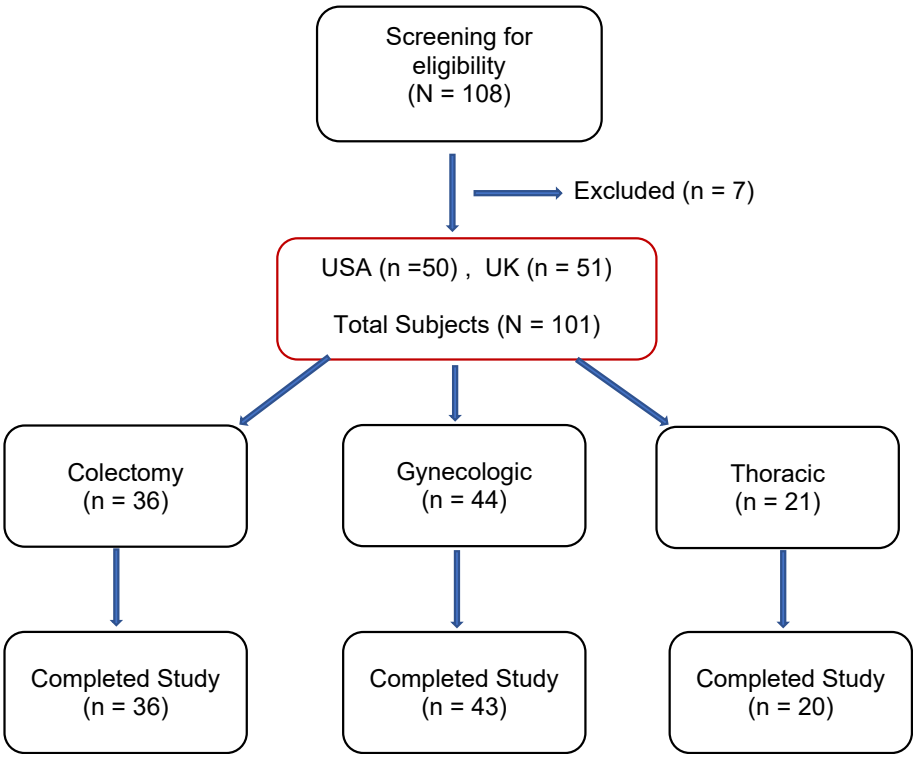

Fig. 1. Subject Selection and Procedure Groups. All 101 subjects who underwent surgery with the test device were included in analyses. Sites in the United Kingdom (UK) enrolled 51 subjects, and 50 were enrolled in the USA.

Table 1
Subjects' preoperative characteristics.

Characteristic	Colectomy N = 36	Gynecologic N = 44	Thoracic N = 21	Total N = 101
Age at Consent (years)				
Mean (SD)	60.9 (13.4)	59.9 (13.3)	67.6 (6.2)	61.8 (12.5)
Median (Min, Max)	61.5 (32.0, 89.0)	61.0 (28.0, 88.0)	67.0 (57.0, 85.0)	63.0 (28.0, 89.0)
Gender				
Male	19 (52.8%)	0 (0.0%)	14 (66.7%)	33 (32.7%)
Female	17 (47.2%)	44 (100.0%)	7 (33.3%)	68 (67.3%)
Race				
White	35 (97.2%)	40 (90.9%)	21 (100.0%)	96 (95.0%)
Black/African American	1 (2.8%)	1 (2.3%)	0 (0.0%)	2 (2.0%)
Native Hawaiian	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (1.0%)
Asian	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (1.0%)
Not reported	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (1.0%)
Body Mass Index (kg/m^2)				
Mean (SD)	27.6 (7.8)	28.1 (6.7)	27.5 (5.9)	27.8 (6.9)
Median (Min, Max)	25.8 (16.7, 52.5)	27.2 (17.7, 44.9)	26.8 (19.2, 43.4)	26.2 (16.7, 52.5)
Diabetes	4 (11.2%)	5 (11.4%)	1 (4.8%)	10 (9.9%)
Obesity	2 (5.6%)	1 (2.3%)	1 (4.8%)	4 (4.0%)
Hypertension	16 (44.4%)	16 (36.4%)	7 (33.3%)	39 (38.6%)
Current Smoker	5 (13.9%)	6 (13.6%)	2 (9.5%)	13 (12.9%)
Former smoker	15 (41.7%)	17 (38.6%)	13 (61.9%)	45 (44.6%)

(SD) standard deviation; (Min, Max) range minimum and maximum.

Table 2
Specific procedures performed.

Procedure Group	Specific procedure	n (%)
Colectomy N = 36	Right colectomy (or ileocolectomy)	9 (25.0%)
	Low anterior resection	7 (19.4%)
	Sigmoid colectomy	7 (19.4%)
	Hartmann procedure	2 (5.6%)
	Left colectomy	1 (2.8%)
	Sub-total colectomy	1 (2.8%)
	Other	9 (25.0%)
Gynecologic N = 44	TAH/subtotal with bilateral salpingo-oophorectomy	19 (43.2%)
	TAH/subtotal with unilateral salpingo-oophorectomy	3 (6.8%)
	TAH/subtotal with bilateral salpingectomy	3 (6.8%)
	Bilateral salpingo-oophorectomy	3 (6.8%)
	Other	16 (36.4%)
Thoracic N = 21	Transthoracic esophagectomy	15 (71.4%)
	Other	6 (28.6%)

(TAH) total abdominal hysterectomy.

for additional hemostasis in all Grade 4 transections except for one instance of hemoclip placement.

For all transections, 300 (95.5%) were reported as having no sticking tissue. All 14 cases where sticking was identified were rated as "slight sticking requiring activation of the ABP device to release tissue", with no cases requiring counter-tension or counter-tension and extensive force. Although investigators could use their method of choice for tissue dissection and isolation of vessels, 78 (77.2%) procedures overall utilized the ABP test device for this purpose. Use of the test device for tissue dissection was done in (95.5%) of gynecologic procedures, (77.8%) of colectomy cases, and (38.1%) of thoracic procedures.

3.4. Adverse events

This study collected all adverse events (AEs) that were determined to be specifically related to either the study procedure (n = 122) or the test device (n = 4). A total of 43 (42.6%) subjects reported at least one AE meeting these criteria: 15 (41.7%) colectomy subjects; 20 (45.5%) gynecologic subjects; and 8 (38.1%) thoracic subjects. The 4 device-related AEs included hematoma and hypotension in 1 (2.8%) colectomy subject, procedural pain in 1 (2.3%) gynecologic subject, and a superficial thermal burn in 1 (2.3%) gynecologic subject. The burn was approximately 0.5 cm in length in the vulvar area and required no intervention. It was thought to have been caused by the test device, whereas the remaining 3 events were considered to have an unlikely relationship to the device. Twelve (11.9%) subjects experienced at least one serious adverse event (SAE) during the study. None of the 15 total SAEs were related to the study device. All AEs were also classified for clinical relevance per the Clavien-Dindo (CD) surgical complications scale (Table 5) [13]. Of 122 procedure-related AEs, 107 (87.7%) were scored as either CD Grades I or II. Higher CD grades (≥Grade III) were assigned for 15 (12.3%) events, all from the colectomy and thoracic groups. There were 3 (2.5%) AEs classified as Grade IVa, consisting of two cases of respiratory failure and one kidney injury. Importantly, all 4 device-related AEs were rated as mild in severity and were classified as Clavien-Dindo Grade I complications.

3.5. Questionnaires

The device questionnaires indicated that only one hand was required to operate the ABP test device in 98 (97%) total procedures across all three groups. In addition, the need to reposition the device or change hand position to activate the it was not required in 86.1% and 94.1% of procedures, respectively. Finally, the ABP study device was considered easier to fire by 73.3% of (11 of 15) participating surgeons, compared to previously used advanced bipolar instruments.

4. Discussion

This study included three procedure groups and 314 total vessel transections performed with the ABP test device. With respect to the primary endpoint measure, all 68 vessel transections in the colectomy group were Grade 3 hemostasis or lower, and first pass hemostasis was achieved (Grades 1 and 2 combined) with no intervention required in 67 (98.5%) transections. The most common vessel transected in the colectomy group was the IMA (n = 15), and there were no cases of observed bleeding for this major artery. Similarly, for right-sided colon resections, the primary ligated

Table 3
Vessel hemostasis grading and operative data.

Variable	Colectomy N = 36	Gynecologic N = 44	Thoracic N = 21	Total N = 101
Total Number of Vessels Transected	68	156	90	314
Hemostasis Grading Scale				
Grade 1	63 (92.6%)	126 (80.8%)	81 (90.0%)	270 (86.0%)
Grade 2	4 (5.9%)	14 (9.0%)	3 (3.3%)	21 (6.7%)
Grade 3	1 (1.5%)	7 (4.5%)	3 (3.3%)	11 (3.5%)
Grade 4	0 (0.0%)	9 (5.8%)	3 (3.3%)	12 (3.8%)
Vessels Scored Grade 3 or lower	**68 (100.0%)**	**147 (94.2%)**	**87 (96.7%)**	**302 (96.2%)**
Exact 95% Confidence Interval	94.7%,100.0%	89.3%,97.3%	90.6%,99.3%	93.4%,98.0%
Grade 3 Compressions	0	3	0	3
Grade 3 Touchups				
Number Using Monopolar	1	3	2	6
Number Using ENSEAL X1	0	7	1	8
Procedure Duration (hrs)				
Mean (SD)	4.1 (2.2)	2.4 (1.1)	4.5 (1.7)	3.4 (1.9)
Median (Min, Max)	3.7 (1.6, 10.5)	2.4 (0.8, 4.6)	5.0 (1.4, 7.0)	3.0 (0.8, 10.5)
Intraoperative Blood Loss (ml)				
Mean (SD)	407.5 (771.0)	436.4 (420.0)	275.3 (231.7)	393.8 (548.4)
Median (Min, Max)	200.0 (20.0, 4500.0)	300.0 (85.0, 2500.0)	125.0 (100.0, 900.0)	210.0 (20.0, 4500.0)
Intraoperative Transfusion Required[a]	2 (5.6%)	4 (9.1%)	1 (4.8%)	7 (6.9%)
Presence of inflamed or Calcified Tissue/Vessels[a]	10 (27.8%)	4 (9.1%)	1 (4.8%)	15 (14.9%)
Length of Stay (nights)				
Mean (SD)	8.6 (5.7)	3.3 (2.4)	12.7 (6.1)	7.1 (5.9)
Median (Min, Max)	7.0 (2.0, 29.0)	3.0 (1.0, 11.0)	11.0 (5.0, 26.0)	5.0 (1.0, 29.0)

[a] Percentage calculated using the total procedures in each group as denominator.

Table 4
Hemostasis Grade 4 transections and hemostatic interventions used.

Grade 4 Vessels (n)	Additional Hemostatic Product Used
Left uterine artery & vein (2)	Suture
Left uterine artery (2)	Suture
Right uterine artery (4)	Suture
Right ovarian artery (1)	Suture
Short gastric (2)	Suture (1); Hemoclip (1)
Gastroepiploic (1)	Suture

Table 5
Clavien-dindo (CD) classification of AEs.

Variable	Colectomy N = 36	Gynecologic N = 44	Thoracic N = 21	Total N = 101
Procedure-Related				
AEs	55	43	24	122
SAEs	6	2	7	15
CD Score n (%)[a]				
Grade I	38 (69.1%)	34 (79.1%)	5 (20.8%)	77 (63.1%)
Grade II	12 (21.8%)	9 (20.9%)	9 (37.5%)	30 (24.6%)
Grade IIIa	1 (1.8%)	0 (0.0%)	8 (33.3%)	9 (7.4%)
Grade IIIb	2 (3.6%)	0 (0.0%)	1 (4.2%)	3 (2.5%)
Grade IVa	2 (3.6%)	0 (0.0%)	1 (4.2%)	3 (2.5%)
Device-Related				
AEs	2	2	0	4
SAEs	0	0	0	0
CD Score n (%)[a]				
Grade I	2 (3.6%)	2 (4.7%)	0	4 (3.3%)

[a] Percentage of total AEs in each procedure group, including SAEs.

vessels included ileocolic, middle and right colic, none of which exhibited any bleeding issues. Among 156 total vessel transections in the gynecologic group, 89.7% were first pass hemostasis. The ABP device was particularly useful in gynecologic cancer cases where omentectomy was required, with each of the 17 omental vessel transections rated as Grade 1 hemostasis. Gynecologic procedures also included 68 and 66 transections of uterine and ovarian arteries, respectively, which were the most common vessels transected in this group. Obvious intraoperative bleeding during hysterectomy may commonly occur from loss of hemostatic control of the vascular pedicles associated with these vessels [14]. In this study, suture was utilized for intervention in all 9 instances of uterine or ovarian artery (Grade 4) bleeding, which provided successful hemostasis in each case. The other three occurrences of Grade 4 hemostasis occurred in thoracic procedures, but overall this group also exhibited first pass hemostasis in a majority (93.3%) of transections. Among secondary endpoint measures, surgeons' responses to questionnaires indicated ease of use of the test device in terms of positioning and firing relative to previous advanced bipolar devices. Tissue sticking, which can inhibit delivery of energy to targeted vessels and disrupt sealing, was minimal.

The type and frequency of AEs, including those reported as serious, were consistent with the types of procedures performed in the study. For the events that were considered device-related, 3 of the 4 were identified as having an unlikely relationship to the study device. Moreover, none of the device-related AEs were serious. Classification of AEs according to the CD surgical complications scale indicated that a majority of AEs across all three procedure groups were CD Grades I or II. No AEs from the gynecologic group were scored higher than CD Grade II, despite a high proportion of extensive operations such as abdominal hysterectomy with salpingo-oophorectomy and 9 occurrences of hemostasis Grade 4 transections. Importantly, each of the 4 device-related AEs recorded in the study were CD Grade I. Thus, the test device was determined to have an acceptable safety profile among the three open procedure groups.

Median intraoperative blood loss for all subjects was 210 ml and given the prevalence of complex open operations in this study, it was not surprising that intraoperative transfusions of blood or blood products were required in 7 (6.9%) procedures overall. Only one AE was reported (anemia) in which transfusion was necessary as the action taken, and this non-serious event was scored as Clavien-Dindo Grade II. In addition, one subject from the colectomy group who underwent a Hartmann's procedure, experienced intraoperative blood loss of 4500 ml that did require transfusion intraoperatively as well as postoperatively prior to discharge. This 4500 ml blood loss was a result of intra-operative issues that were not related to the study device or the specific transection that the

study device was used for. For gynecologic surgeries, median blood loss was 300 ml, and intraoperative transfusions were performed in 4 (9.1%) procedures. Estimated median intraoperative blood loss during abdominal hysterectomy with or without salpingo-oophorectomy has been reported as 200–480 ml, with transfusion required in up to 9.3% of cases [15,16]. Thus, blood loss results from the gynecologic group are consistent with published data. Similarly, median blood loss during open transthoracic esophagectomy was reported from 325 to 568 ml [17,18], which is higher than the median volume observed in the current study for thoracic procedures (125 ml). Taken together, the findings in this study are consistent with effective hemostasis performance by the ABP device.

Strengths of the study include the prospective, multi-center design and a substantial number and variety of vessels transected among three procedure groups. The use of devices in different procedures is considered important in order to replicate real-world practice. In addition, all sites used consecutive screening and enrollment as well as broad inclusion/exclusion criteria to provide a representative patient sample. The primary limitation was the single-arm design (i.e. no comparator device) for evaluating performance of the ABP test device. Although the novel hemostasis grading scale certainly provided detail with regard to occurrence and extent of vessel bleeding, it should be further studied in order to confirm reproducibility and overall usefulness in surgical applications.

5. Conclusion

To our knowledge, this study represents the first published large clinical analysis of the ABP device. Considering the types and frequencies of AEs, the overall safety profile, and the rate of first pass hemostasis, the ENSEAL® X1 Large Jaw Tissue Sealer was considered effective for open colectomy, thoracic, and gynecologic surgery applications.

Ethical approval

The protocol and consent form were approved by each investigator's Institutional Review Board or Independent Ethics Committee, and informed consent was obtained for all subjects.

Funding

Financial support/sponsorship for this study was provided by Ethicon Endo-Surgery, Inc. The sponsor was responsible for study design, monitoring, analysis of data, and preparation of the manuscript.

Author contribution

Study design: MLS and JRW.
Data acquisition: JS, DA., FS, BH, AS, GF, SA, SF, HP and BR.
Analysis and interpretation: MLS, JRW, DWS, and RF.
Drafting of manuscript: DWS.
Review and revision: MLS, JRW, RF, JS, DA, FS, BH, AS, GF, SA, SF, HP and BR.
Final approval: all authors.
Contributors: Kenneth Kesler and Alyssa Fajardo, Indiana University, USA; Stephen Ward, University Hospitals Birmingham, UK; James May, Royal Infirmary of Edinburgh, UK. Each of these investigators contributed data to this study.

Conflict of interest statement

M.L.S, J.R.W, D.W.S and R.F are employed by Ethicon Endo-Surgery, Inc. The other authors do not declare any competing interests.

Guarantor

Jason R. Waggoner PhD, Ray Fryrear II MD.

Research registration number

Unique Identifying number or registration ID: NCT03441178.

Data statement

The data that has been used is confidential.

Acknowledgements

The authors wish to thank the following investigators/surgeons for their contributions of data to this study: Kenneth Kesler, Indiana University, USA; Alyssa Fajardo, Indiana University, USA; Stephen Ward, University Hospitals Birmingham, UK; James May, Royal Infirmary of Edinburgh, UK.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2020.03.007.

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